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NATIONAL PATIENT SAFETY AUTHORITY

TECHNOLOGY INFRASTRUCTURE BLUEPRINT

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EXECUTIVE SUMMARY

Healthcare information has been largely digitized over the last decade as a result of Electronic Health Record (EHR) adoption, and yet this data has not yet been harnessed to reduce the harms caused to patients. An estimated 250,000 patients die due to medical errors every year, making it the third leading cause of death behind heart disease and cancer (Ref. 1). To address this problem and take advantage of the digitization of healthcare, the Jewish Healthcare Foundation (JHF) partnered with the Network for Excellence in Health Innovation (NEHI) in an initiative called Swerve to define a new agency to integrate and advance patient safety efforts, the National Patient Safety Authority (NPSA). In the JHF policy recommendations, the NPSA is modeled after the National Transportation Safety Board (NTSB) with investigative authority, and is envisioned to drive research and development and policy recommendations to be carried out by other existing regulatory agencies.

The NPSA policy objectives and proposed structure are laid out in a companion document (Ref. 2). This document provides a technology blueprint to support the NPSA, with primary objective of outlining many technological capabilities that exist today, in healthcare and other industries that support the feasibility of the NPSA carrying out its mission. Technology developments together with a host of regulatory developments have created the opportunity to build a better, safer healthcare delivery system and substantiate that the time is now to move forward with the NPSA.

The five key technical areas of focus that support the formation of an NPSA are:

1. A comprehensive, safety centric, quality measurement framework that includes near real time error detection, harm measures, and risk/hazard based measures.
2. Creation of standardized approaches to artificial intelligence (AI) and automation at the point of care and health system organization level.
3. Harnessing and expanding a national communications infrastructure for health information exchange to collect pertinent data from across the ecosystem.
4. Construction of an analytics infrastructure for analysis and research of patient safety across the ecosystem to investigate systematic issues, and substantiate best practices for standardization.
5. Creation of a patient safety focused surveillance infrastructure across the industry ecosystem and new command and control capabilities at the health system level.

With these five components, the NPSA can influence patient safety from the point of care to the industry wide ecosystem, and move patient safety from a voluntary reporting, post facto, retroactively measured phenomenon to a proactive, predictive, and prescriptive 21st century analytics infrastructure driven by data science.

Technology standards and regulatory requirements for health exchange and integration and the introduction of AI pave the way for use of data to drive patient safety. Data infrastructure, collection, and analysis approaches heavily used in other industries, and increasingly used in healthcare, are available to usher in the next generation of patient centric and more proactive all-cause harm prevention.

1. INTRODUCTION

Approaches to improve patient safety have come a long way since the Institute of Medicine published the landmark report *To Err is Human* two decades ago (Ref. 3) and measuring care quality and patient safety is more mature than ever with the application of modern tools and technologies. However, patient safety measurement is still overwhelmingly manual, retrospective, voluntary, anonymous, and incident-driven, which means improvement initiatives are still overwhelmingly reactive instead of proactive. In addition, large-scale efforts to better measure patient safety have been top-down regulatory approaches that require certain data reporting. Bottom-up approaches using local data to inform what data regulators should collect and analyze offer an innovative approach to measuring and improving patient safety at a national level.

While approaches to patient safety have not systematically changed, many other aspects of healthcare have continued to evolve. The technology, regulatory, and reporting frameworks that have evolved over the last 20 years since the American Reinvestment and Recovery Act (ARRA) Health Information Technology Economic and Clinical Health (HITECH) Act have laid the groundwork for the bold objectives of the National Patient Safety Authority (NPSA). Specifically, interoperability initiatives of the Office of the National Coordinator (ONC) from the early days Electronic Health Record (EHR) Meaningful Use requirements, to the more recent Trusted Exchange Framework and Common Agreement (TEFCA), the Information Blocking Final Rule, and the CMS Interoperability Rule have set the stage for an interoperable access to health data on a national scale.

On another track of health reform and innovation, CMS driven Alternate Payment Models (APM) has progressed through multiple generations of Accountable Care Organizations (ACO) dating back to 2012 and through 2015. During that time, Meaningful Use metrics were absorbed into the Quality Performance Plan as metrics in the Merit-based Incentive Payment System (MIPS) as part of the Medicare Access and Children Health Insurance Plan (CHIP) Reauthorization Act. Meaningful Measures 2.0, launching in 2020, coupled with the latest instantiation of the ACO, the Direct Contracting ACO (Ref. 4) are the latest steps in a journey that has created substantial data for measuring healthcare quality.

At the same time, the Food and Drug Administration (FDA) has been modernizing both regulations and medical device safety surveillance infrastructure over the last 10 years. Central to this modernization is the Sentinel program (Ref. 5), launched in 2007 via the FDA Amendments Act (FDAAA). This resulted in launch of the Sentinel system in 2016, and opening of an innovation center in 2019. Sentinel is largely an identical model for what the NPSA will require because it created a distributed data collection infrastructure to identify anomalous signals of adverse medication issues and supports research that is separate from the regulatory function of the coordinating center. Another important development in FDA regulation is the Precertification program, which lays groundwork for introduction of AI at both the point of care and the hospital system level through new vendor solutions leveraging the considerable new data available from EHRs.

All of these developments, together with technological advancements in healthcare data infrastructure, collection, and analysis approaches heavily used in other industries are available to

usher in the next generation of all-cause harm prevention to realize the opportunities for a safer, more proactive, patient safety focused care delivery system. The objective of this white paper is to outline the key tenants of such an infrastructure, and to provide a blueprint for implementation of a National Patient Safety Authority.

2. NPSA CONCEPTUAL FRAMEWORK

The Jewish Healthcare Foundation (JHF), through its operating arm the Pittsburgh Regional Health Initiative (PRHI), convened 120 American leaders in health reform to develop a concept for implementation of an NPSA, modeled after the National Transportation Safety Board (NTSB) (Ref. 2). Such an agency would have the same stature that the Office of the National Coordinator (ONC) has had over interoperability, CMS has had over transition from volume to value in care delivery, and that FDA has had for drug and medical device regulation. Figure 1 illustrates the overall conceptual framework for the NPSA, mapping NPSA key responsibilities against different layers of the healthcare ecosystem, as defined in the National Academy of Medicine's 2016 interoperability framework (Ref. 6).

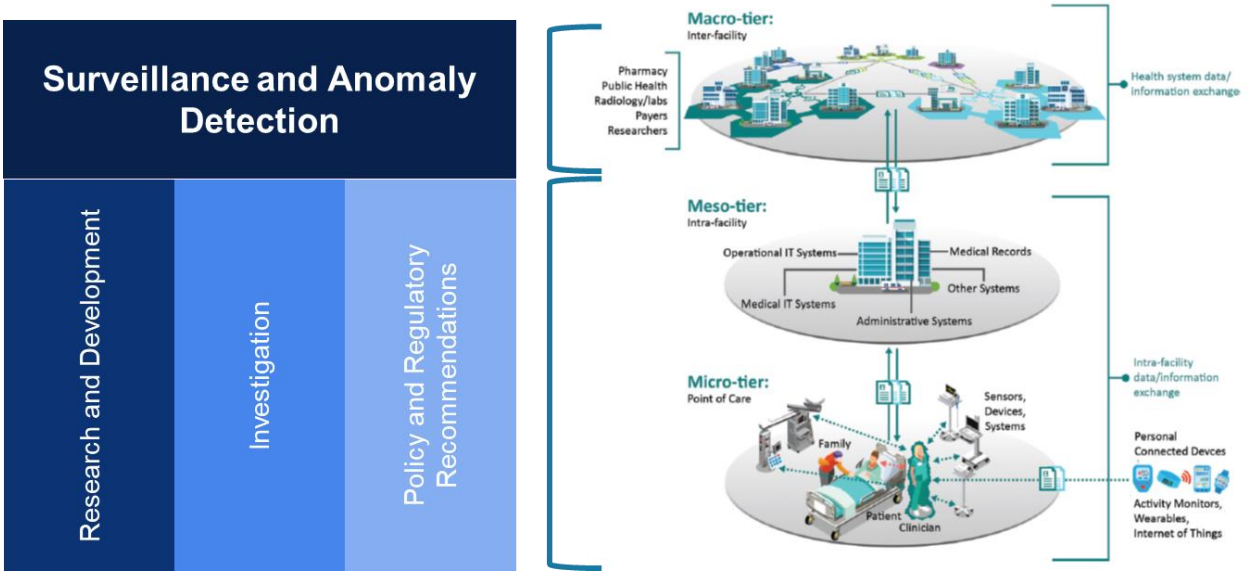

Figure 1: NPSA Technical Blueprint Alignment with Healthcare Industry Architecture

NPSA surveillance will collect data at the Macro-tier level, in order to look for anomalies and deviations from baseline performance at a national healthcare system level. The R&D, investigative authority, and policy and regulatory guidance role of the NPSA will be directed at the Meso-tier (health system), and Micro-tier (point of care).

As outlined in the JHF's policy proposal for the NPSA , the new entity will have responsibilities for surveillance, investigations of patient harms, and research and development of technologies for prevention of patient harms. The NPSA will also collaborate with industry and across the healthcare ecosystem to develop new standards of care that can be implemented at scale.

This white paper focuses on the technical infrastructure required for the NPSA to be successful, and provides a path toward achieving NPSA aims. The infrastructure required for the NPSA to be successful includes the following technical components:

1. A comprehensive, safety centric, quality measurement framework that includes near real time error detection, harm measures, and risk/hazard based measures..
2. Creation of standardized approaches to AI and automation at the point of care (Micro-tier) and health system organization level (Meso-tier), including predictive capabilities to prevent harms based on risk based measurement.
3. Harnessing and expanding a national communications infrastructure for health information exchange to collect pertinent data from across the ecosystem.
4. Construction of an analytics infrastructure for analysis and research of patient safety across the ecosystem to investigate systematic issues, and substantiate best practices for standardization.
5. Creation of a patient safety focused surveillance infrastructure across the industry ecosystem (Macro-tier) and new command and control capabilities at the health system level (Meso-tier).

With these five components, the NPSA can influence patient safety from the Micro to the Macro tier in Figure 1, and move patient safety from a voluntary reporting, post facto, retroactively measured phenomenon to a proactive, predictive, and prescriptive 21st century analytics infrastructure driven by data science. Support for translational and implementation science to apply findings to change care practice patterns is another requirement in addition to the technological components above, though exploring this requirement is beyond the scope of this paper. Similarly, changes to medical education system to evolve clinician skills and understanding of more intelligent, AI based medical systems is essential, but not the addressed in this white paper.

Fundamental to the success of the NPSA is collaborative R&D with health systems, which will create standards around minimum expectations on how data is used at the point of care. While this approach is not novel in healthcare, it is not the current approach used for patient safety, which is top down, and retrospective in nature. Investigation into patient harms using an extensive diagnostic and forensic big data infrastructure will support feasibility of health ecosystem wide deployment of improvements and then inform policy and regulatory recommendations. These recommendations will not be governed by the NPSA, but will flow through other regulatory and accreditation agencies, including ONC, the Agency for Healthcare Research and Quality (AHRQ), FDA, CMS, and the Joint Commission.

Surveillance of Meso-tier risk based measures collected across the Macro-tier would inform areas where improvement would have the highest impact on patient safety and inform R&D, and inform the interoperability strategy required to achieve this end. The following sections detail how this can be accomplished with reference to existing technology and capabilities that exist today.

3. MEASUREMENT FRAMEWORK

A significant number of measures and taxonomies that relate to patient safety already exist today. Unfortunately, the many sources of patient safety information that are essential in informing quality improvement are spread across multiple domains and systems. These measures tend to be narrowly focused on medical errors vs. broader measurement frameworks that include risk, error and harm (Ref. 7). They also require a significant amount of after the fact manual inspection of events and are not analyzed across the entire health ecosystem.

AHRQ has already done the heavy lifting required to converge many of the existing taxonomies into a single ontological framework for reporting medical errors (Ref. 8). The ontology aligns multiple existing taxonomies including the National Coordinating Center for Medication Error Reporting and Prevention (NCCMERP) Taxonomy, the Preliminary Taxonomy of Medical Errors in Family Practice (PTFP), the Joint Commission Sentinel Events Reporting database (JSER), and the Joint Commission Patient Safety Event Taxonomy (PSET).

It is critical that the NPSA have the charter not just to align the existing taxonomies, but also to develop a more comprehensive approach based on the principles identified in the AHRQ ontology framework. The resulting framework would enable identification and analysis of medical error events and include the following attributes:

- Covering the full range of settings in which health care takes place, not just hospitals
- Capturing the full richness of the domain of risks/hazards, errors, and adverse events
- Enabling the capture of data from all sources, e.g., health system delivery and processes, not just medical device or drug use oriented), to include environment/setting/contextual variables about hazards
- Capturing accurate timing/chronology of situations and events
- Making data available in timely fashion relative to the mitigation action the data analysis informs
- Enabling analysis that support identification of strategies for improvement by all users, e.g., healthcare providers, quality organizations, payers (CMS and commercial), and policy makers

In addition to the roadmap laid out by AHRQ, the NPSA will also leverage existing efforts by CMS to revamp measures related to Hospital Acquired Conditions (HAC), and to move these measures from claims based lagging indicators to Electronic Clinical Quality Measures (eCQMs) derived directly from EHR data, creating the opportunity for closer to real-time availability of these measures. These HACs need to be expanded to include all harms caused by the healthcare system, not just those in hospitals, and would be better termed Healthcare Acquired Conditions. A NPSA would be in a better position to harmonize the efforts of AHRQ and CMS into a more comprehensive, data driven prioritization of measurement efforts.

The Institute of Healthcare Improvement (IHI) and has also developed a taxonomy for medical errors and harms through development of the IHI Global Trigger Tool (GTT) which set definitions for all-cause harm detection. The World Health Organization (WHO) published the International

Classification for Patient Safety (ICPS) in 2009, which described a conceptual framework to which existing regional and national classifications can relate data elements, and lays the conceptual foundation for the Minimal Information Model of Patient Safety (MIM PS) incident reporting (see Appendix A). This work defined standard information elements for event reporting as a basis for comparison across healthcare systems, particularly in an international context. The IHI GTT and WHO MIM PS are taxonomies and classification systems designed for manual incident reporting and retrospective chart review, though NPSA could adapt them to suit automated information capture and analysis and supplement the AHRQ ontology with hierarchical taxonomies, terminology sets, and standard data element definitions. These common standards for monitoring, reporting, classifying, analyzing, and interpreting patient safety incident data lay the groundwork for standardizing a data infrastructure to drive advanced analytics.

Today's patient safety measures are typically either error based metrics, or injury based metrics. As pointed out in *Risk-Based Patient Safety Metrics* (Ref. 7), safety science in other industries includes a third type of measure that does not exist broadly in healthcare, called risk based measures. Risk based measures quantify risk in terms of hazards that exist in the system or treatment protocol where errors could lead to patient injury, vs. measuring errors or injury's as current systems of measures in patient safety in existing systems today. Risks are the "stories behind errors and injuries" and provide deeper insight into why an error occurred to drive specific improvements to eliminate as many risk factors as possible (Ref. 7).

An example of risk-based measurement in health care is treating failure of compliance to clinical practice guidelines as a system risk. Perhaps the most famous tool to measure and reduce non-compliance was the development and implementation of a central line associated bloodstream infection (CLABSI) checklist-based bundled (Ref. 9). Reframing known patient safety errors and harms from surveillance measurement in terms of the root cause risks that lead to them paves the way for systemic changes that sustainably transform and re-engineer care processes to prevent errors and harm rather than merely mitigating their effects retrospectively. Error and harm measurements are beneficial to track in conjunction with risk-based measures, as their trends indicate success of risk elimination efforts, though they are inferior to risk-based measures as drivers of specific improvements.

The challenge of risk-based measurement is quantification. Vast amounts of data, intricately integrated, are required for a true systems picture of the various risk factors in the surrounding environment of patient care. The first step is understanding risks and the relationship between system variables such as ambient environmental factors, local populations and processes, and individual characteristics of both patient physiology as well as patient and provider behavior patterns. To date, even proactive risk assessments (e.g., Failure Modes and Effects Analysis, FMEA) are typically qualitative in nature, which is a valid approach but time consuming and difficult to scale to the scope and complexity of care delivery, especially given the inherent variation in care processes and contexts across care locations.

While risk is a common concept in health care, the focus of traditional 'risk management' hospital departments is typically on protecting organizations or individuals from financial loss through malpractice claims, for example, and is commonly a separate entity within a health care system from a quality or safety department for legal reasons. The classic health care 'risk management'

paradigm is about whether or not the standard of care was met or whether a provider's medical judgement is in question. Meanwhile, a patient safety paradigm focuses on to what degree the system is designed to produce quality care and desirable patient outcomes, where blame is not ascribed to individuals but thorough systematic analyses for root causes and failure modes and effects determine system weaknesses, or hazards, which led to error or harm. Legally, information can flow from risk management activities (e.g., mortality and morbidity conferences, legal investigations) to patient safety activities but not vice versa, which creates organizational and informational siloes that may hamper patient safety efforts or spread resources thinly to manage regulations and requirements from both paradigms.

To advance patient safety measures, the NPSA will take responsibility for building a cohesive strategy to rationalize whether or not the existing measures are useful and sufficient, and to define new measures that may be required, including the introduction of safety engineering, systematic risk-based measures. The NPSA will work with ONC, CMS and FDA as coordinating agencies with regulatory authority as a mechanism to create the right regulatory framework to implement and enforce compliance.

4. AI AND AUTOMATION

Algorithms have been underlying sophisticated alarms and alerts derived from medical device, lab, and Computer Physician Order Entry (CPOE) systems for more than a decade. Health systems and solutions providers have continued to evolve these capabilities using more sophisticated tools like machine learning (ML), but have done so despite hurdles presented by lack of interoperability and integration, and the need for processing real time vs. charted EHR data. Thus far, these advances have been considered innovations for health systems with sufficient resources to hire data scientists and invest in integration, or a relatively small number of vendors that could pass FDA hurdles to generalize and productize sufficiently well performing algorithms in operational clinical contexts. Based on favorable regulatory developments and advancement in machine learning capabilities, these technologies are poised to become an integral part of the health technology landscape.

There are numerous successes with these types of applications, including for example Modified Early Warning Systems (MEWS) and sepsis detection. The early detection of physiological deterioration to reduce in-hospital Cardiopulmonary Arrest (CPA) as a national patient safety goal has resulted in the formation of Rapid Response Teams (RRT) to respond to patient events. Traditional application of MEWS includes assessment of patient data and a scoring system to direct increased monitoring and trigger RRTs when appropriate. Even though MEWS can be somewhat automated with EHR data, it is often not, and in general the scoring system has not been effective (Refs. 10 & 11). Introduction of deep learning and other machine learning techniques has significantly improved advanced warning of patient deterioration by as much as 6 hours (Ref. 12), and reduced mortality by 20 percent (Ref. 13).

Sepsis is another area of where health systems and vendors have sought to improve outcomes using machine learning based algorithms. According to the Sepsis Alliance (Ref. 14), sepsis is the leading cause of death in hospitals, with 1.7 million diagnoses a year and nearly 270,000 people dying from sepsis annually, more than from prostate cancer, breast cancer, and opioid overdoses combined. The costs for sepsis hospitalization and skilled nursing facilities is estimated at $62 billion annually. Sepsis is hard to diagnose and the risk of dying from sepsis increases by as much as 8% for every hour treatment is delayed. This makes sepsis a good target for predictive analytics. Like MEWS, sepsis screening tools based on simple algorithms are not as effective as predictive analytics developed with machine learning techniques. Researchers at the Johns Hopkins University Armstrong Institute and Department of Computer Science developed an algorithm using 54 features commonly available in the EHR, called the Targeted Real-time Early Warning Score (TREWScore). This machine learning based algorithm was shown to identify two-thirds of patients 7 hours before onset of sepsis related organ dysfunction (Ref. 15). A recent meta analysis reviewed 130 models in 28 papers and concluded that these models can predict sepsis onset ahead of time, by typically 3–4 hours (Ref. 16).

There are substantial benefits of more direct monitoring of best practices to identify deviations that could harm patients. This does not require predictive analytics, but rather combining the data available to automatically detect these deviations and present the information to clinicians in a manner that integrates with their workflow and provides clinicians actionable information. The Emerge tool created by JHU/APL in collaboration with the Johns Hopkins Armstrong Institute is an indication of what such a tool could deliver to an ICU (Ref. 17), an environment where best

practice implementation to prevent patient hazards can have a disproportionate effect on patient complications and mortality. The tool monitors 200 ICU patient potential harms and known risk conditions that when elevated are known corollaries for patient injury. These include IHI best practices and many other standards of care, such as how the angle of an ICU bed increases the risk of ventilated associated pneumonia for the patient (Ref. 18).

While the above applications of AI broadly address patient safety by minimizing failure to detect patient risk of a deteriorating condition or deviation from best practices know to reduce medical errors, successful capabilities have been developed to more directly predict patient safety events before they occur. Pascal Metrics, a Patient Safety Organizations (PSO), has already demonstrated the ability to implement AI and automation in the service of improving patient safety in a broader all-cause harm context using advancements in clinical decision support (CDS), and automation. Pascal has created an automated platform that implements the IHI GTT, called the Patient Safety Active Management System (PSAM) (Ref. 19). The IHI tool has existed since 2009, the same year as the ARRA HITECH Act that started deployment of EHRs that now create the data to automate the GTT's manual approach. PSAM has been shown to identify 10X to 20X the patient harms that current manual systems are able to deliver. The NPSA will promote the standardization and use of data created through the digitization of healthcare for these applications.

Making AI based, algorithm driven systems like MEWS, TREWScore, Emerge, and PSAM a required element of health system computerized infrastructure is within reach with the data available in most inpatient healthcare environments. Ability to scale these capabilities economically across the industry requires that minimum standards for interoperability be defined. Interoperability is also a key underpinning of the increased automation that is being envisioned for NETCCN and MDIRA. The ONC has been the driver for interoperability for more than the last decade, and the stage is set for the NPSA to drive interoperability requirements to the next level. See Appendix B for more of a discussion on the interoperability needed for successful implementation of AI for prevention of patient harm.

The NPSA will have the charter to prioritize new capabilities based on readiness of the technology to scale, and readiness of the regulatory and interoperability framework to support broad adoption. To accomplish this, the NPSA will have the responsibility and role of analyzing surveillance data, including error measurement, injury avoidance metrics, and new risk based measures to look for trends and opportunities for increased automation and introduction of AI. NPSA will collaborate with leading healthcare organizations and vendors to test the effectiveness and generalizability of new algorithms and develop standards for operationalizing patient centric, patient safety based AI in healthcare, working with the FDA to help evolve Real World Evidence (RWE) and Precertification criteria, and develop standards for use of AI technology like Machine Learning and Deep Learning. The goal is to create an open source interoperable set of measures that can be implemented by any health system.

It is important to recognize that algorithm based AI is a form of automation. By assembling data and creating additional intelligence using algorithms and visualization, AI reduces the cognitive loading on clinicians. In the case of data intensive environments where clinicians must attend to multiple patients an tasks away from the patient bedside, AI is providing autonomous monitoring of patients. The Philips eICU Tele Critical Care system allows ICU intensivists to safely monitor

up to 150 patients at a time across multiple ICUs and even hospitals by using clinical decision support that identifies which patients and trending toward poor outcomes and predicting adverse conditions based on a substantial amount of data collected from the EHR and directly from medical devices. As shown in Figure 2, clinicians have highly informative alerts that identify which patients need attention and interventions.

Figure 2: Philips eICU uses AI to Automatically Identify Patients at Risk (Ref. 20)

Significant increase in automation are around the corner and there are several examples in current government programs. The U.S. Army's Telemedicine and Advanced Technology Research Center's (TATRC) program for Technology in Disaster Environments (TiDE) includes the establishment of a National Emergency Tele Critical Care Network (NETCCN). The NETCCN Virtual Hospital concept is a cloud-based, stand-alone health information management system that is aimed at providing both capabilities and capacity at the point of need. These capabilities will improve the nation's response to disasters like the pandemic, as well as response to other mass casualty events caused by natural or manmade disasters. TATRC has set up a Device Interoperability and Autonomy Coordinating Center (DIACC) (Ref. 21) with MITRE, JHU/APL, FDA, and other stakeholders to accelerate autonomous capabilities including closed loop control of ventilators and infusion pumps with a goal of achieving autonomy in as early as 5 years (Ref. 22).

Another program funded by the Defense Health Agency (DHA) and led by the Army's Medical Research and Development Command (MRDC) and supported by JHU/APL is the Medical Device Interoperability Reference Architecture initiative. This program aims to develop interoperable capabilities for autonomous medical systems for prolonged care in austere environments and hospitals of the future (Ref. 23). Figure 3 provides a conceptual rendering of autonomous care on the battlefield.

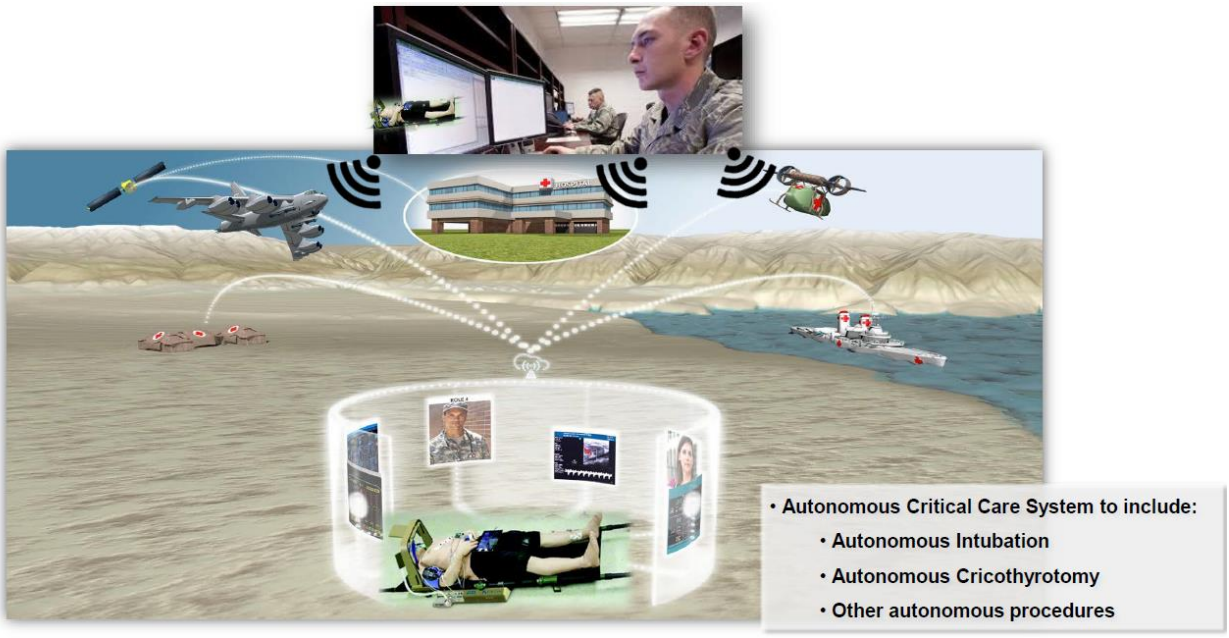

Figure 3: Conceptual Rendering of Autonomous Field Care (Ref. 24)

The commercial healthcare industry can expect to see increased automation and more closed loop control in the future, as innovations from NETCCN and MDIRA, as well as widespread innovation in the commercial sector with advanced robotics and robotic assisted surgical capabilities. These capabilities hold great promise to increase patient safety going forward, but also point to a critical need – a National Patient Safety Authority to insure that the technologies are improving patient safety and not increasing harms.

5. DATA COLLECTION AND BIG DATA INFRASTRUCTURE

There are multiple existing infrastructures in the U.S. healthcare system that can facilitate sharing of data needed to support the NPSA's mission. The ultimate goal is having all information relevant to the safe and effective care of the patient available at the point of care, and all the patient information that across the Macro-Tier available for population and public health applications (Ref. 5).

Examples of current approaches to achieving this include:

- The Health Information Exchange infrastructure, including the Strategic HIE Collaborative (SHIEC), eHealth Exchange, and the CommonWell Health Alliance.
- Existing electronic clinical measure and claims reporting to CMS.
- Medical device and drug safety reporting to FDA.

Figure 4 illustrates the relationship of multiple topologies that exist nationally to facilitate health data exchange. Implementation of TEFCA, the CMS interoperability rule, and Information Blocking provisions of the Cures Act will strengthen this infrastructure. HIEs have played a pivotal role in many regions of the country assisting state public health operations to navigate the COVID-19 pandemic, and are poised to solidify their role as a public utility (Ref. 25). Recent trends also include consolidation between and within states, including the Michigan Health Information Network (MiHIN) merging with Great Lakes Health Connect (GLHC) in 2019 (Ref. 26). In 2020 Nebraska Health Information Initiative (NEHII) and Iowa Health Information Network (IHIN) announcing a merger in the Midwest (Ref. 27), and Colorado's CORHIO and Arizona's Health Current in the West (Ref. 28). CRISP serves Maryland and Washington, D.C., and has expanded to West Virginia, and is poised to expand to other states.

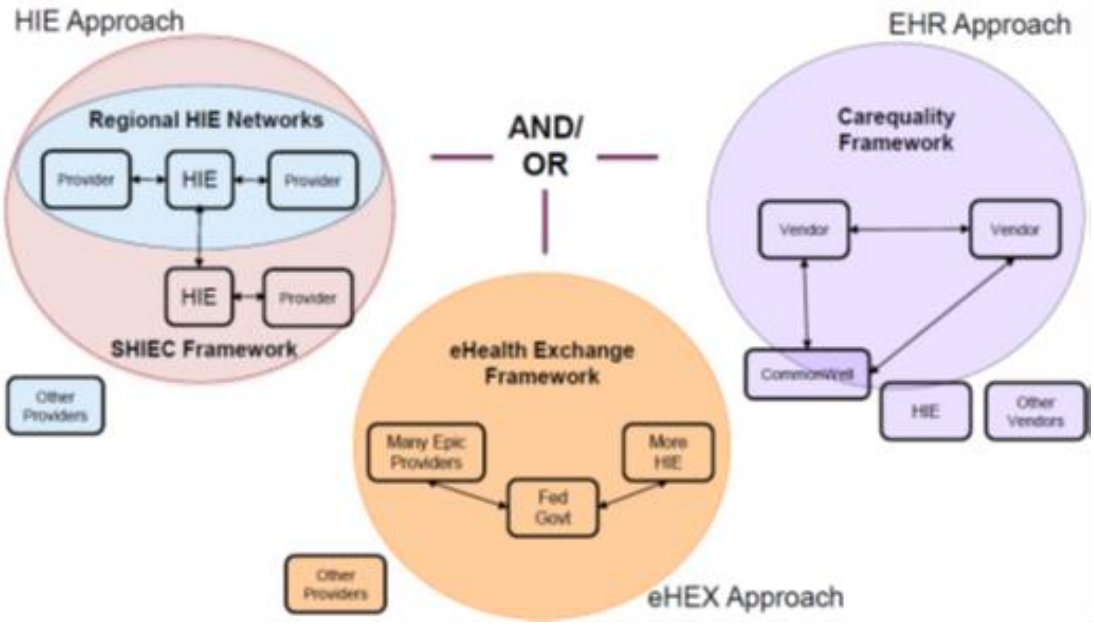

Figure 4: National Health Information Exchange Topology (Ref. 29)

There is already a precedent for leveraging the HIE infrastructure for monitoring healthcare operations in tracking prescriptions for opioids with the Prescription Drug Monitoring Program (PDMP). PDMP is a CDC program implemented at the state level that monitors the prescribing of controlled substances to provide state health authorities timely information about prescribing and patient behaviors intended to facilitate nimble and targeted response to prevent harms associated with the opioid epidemic (Ref. 30). Figure 5 shows the overall topology of the program. The HIEs provide the underlying infrastructure for the data exchange that supports the real time reporting.

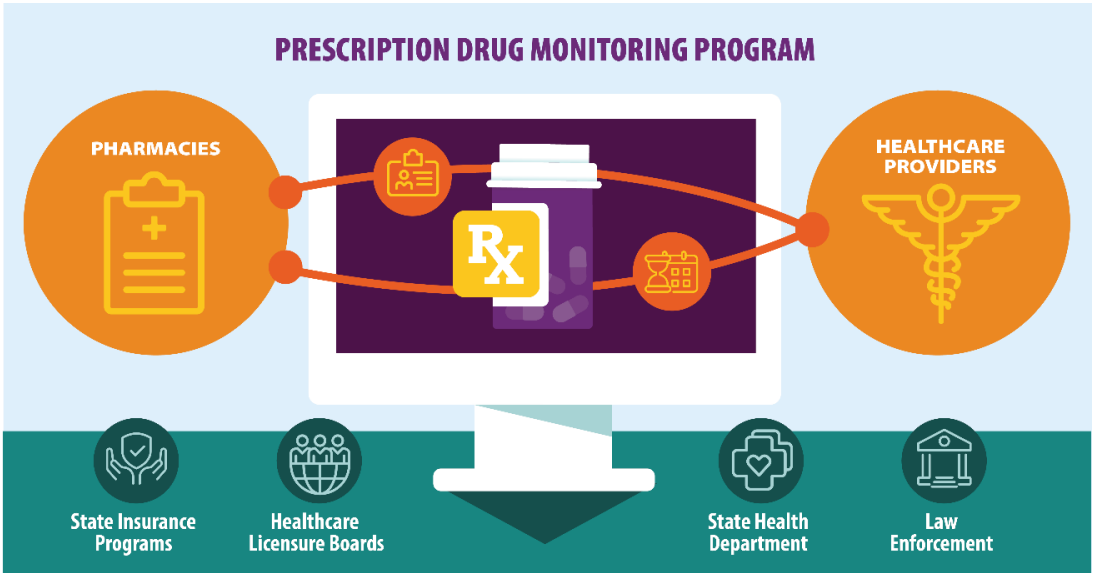

Figure 5: PDMP Program as Precedent for NPSA Infrastructure

HIEs are already integrated to the healthcare ecosystem at the Macro-Tier level for the purpose of providing access to care information from hospitals and practices to facilitate care coordination. This infrastructure can be harnessed to effectively fuel patient safety applications brought forward by the NPSA in the same way the CDC created the PDMP infrastructure.

In May of 2020 the Department of Health and Human Services released the National Health Quality Roadmap, shown in Figure 6, which established the meaningful measures program. Included with measure reform is the goal of making the Quality Measure Enterprise produce accurate, timely and actionable information with sufficient clinical detail for improvement in care. The element of timeliness signals a move from retrospective claims based quality measures to more near real time electronic clinical quality measures (eCQM). Currently CMS is reconstituting Hospital Acquired Condition (HAC) based measures in this direction, which will lay the groundwork for data exchange that will support NPSA objectives.

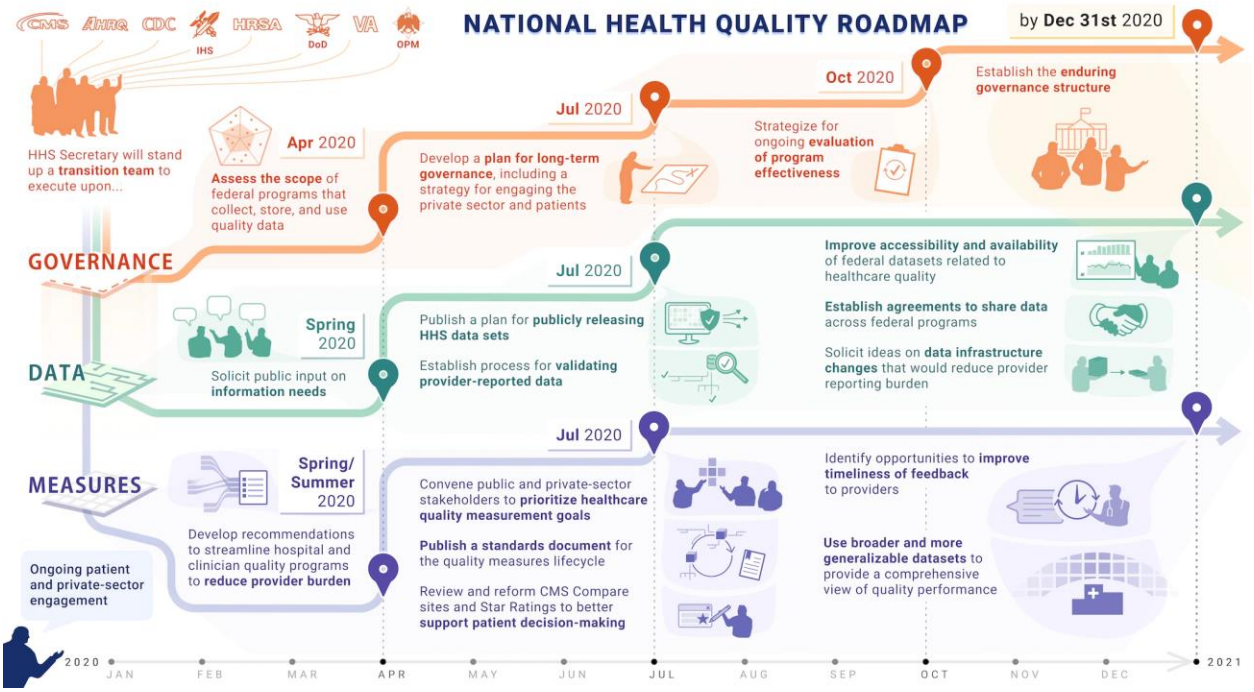

Figure 6: National Health Quality Roadmap (Ref. 31)

While the HIE infrastructure and applications and existing CMS and other HHS reporting infrastructure point to the building blocks for NPSA surveillance functions, the FDA's Sentinel program is perhaps the best example of a data collection infrastructure and governance structure for more probing analysis of healthcare data to find systematic signals of practices and triggers for patient harms.

Figure 7 illustrates the concepts behind this infrastructure. The structure is also in keeping with the intended principles of the NPSA to create the opportunity for deep analysis of Meso-Tier and Micro-Tier data to do investigations of harms and research on industry wide safety improvement opportunities. FDA achieves this by creating Coordinating Centers which are entrusted with data from the participating data partners and separating the FDA regulatory function from the role of data driven research. Thus data provided by participants are protected but the overall system is informed by richer data.

The Sentinel program's structure creates three coordinating centers with different functions: An Operations Center, and Innovation Center, and a Community Building and Outreach Center (Ref. 32). The Operations coordinating center provides surveillance, while the Innovation Center focuses on research, e.g., applying machine learning to the data for discovery of tactics that can be taken at the Micro-Tier level (point of care) to avoid harms, or to create new measures. The Community Building and Outreach Center acts similarly to CMMI's active network of piloting health systems, which accelerates learning and adoption across the Macro-Tier.

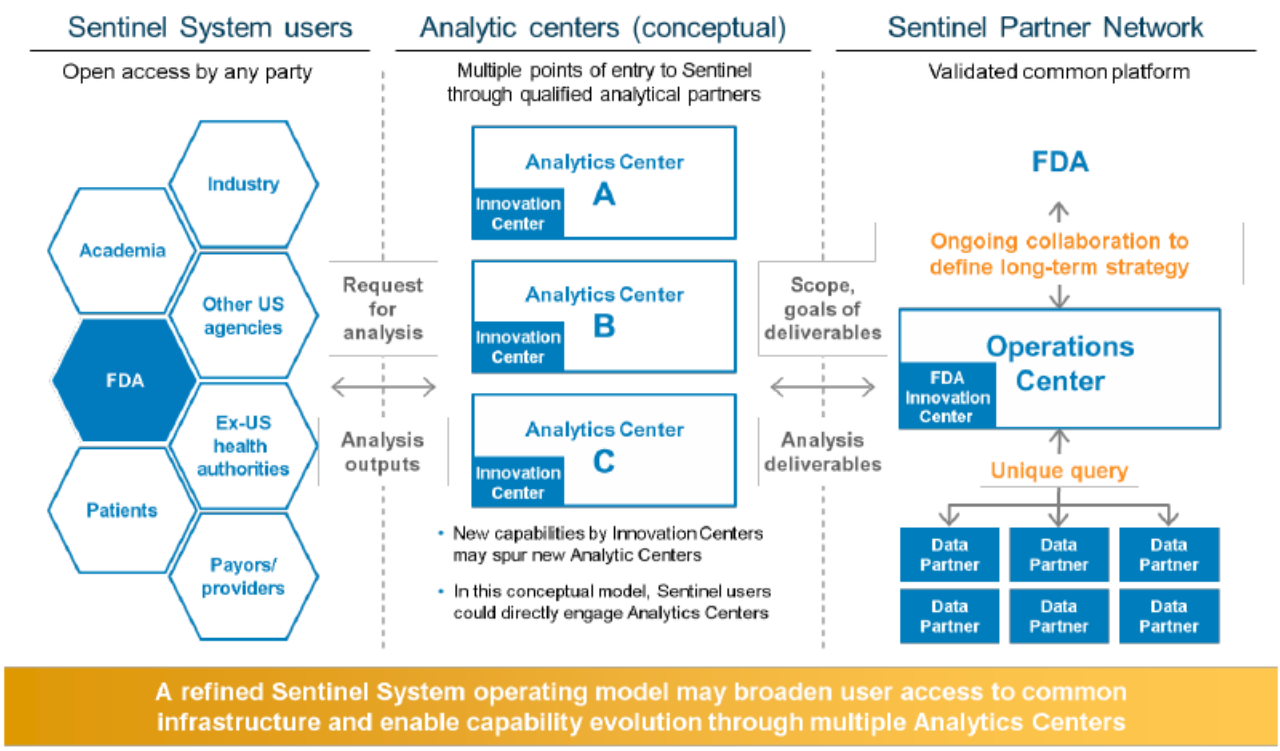

Figure 7: FDA Sentinel Data Collection and Governance Concept (Ref. 33)

The FDA's Sentinel program already separates the role of coordinating centers from the FDA, and is a ready-made platform to expand to support the NPSA's broader vision for patient safety. This would represent a significant expansion of the role of the coordinating centers, but one that is warranted based on the nature of harms that are currently being inflicted on patients across the system. These harms are more systemic than just pharmaceutical and medical devices. Nevertheless, the data being collected already to support Sentinel is ready made for this expansion in scope and a quick start for the NPSA.

The big data infrastructure required supporting the substantial volume of data and the advanced machine learning based analytics is a critically important for the NPSA to analyze harms and trends over time, as well as to support developing new patient centric approaches to patient safety. Big data platforms in healthcare have an additional level of sophistication due to the complexity of data and security and privacy requirements. Nevertheless, there are many successful implementations, including the Johns Hopkins InHealth Precision Medicine Platform, which is hosted on the Microsoft Azure cloud platform (Ref. 34 & 35). The cost effective, scalable data storage and computing available in cloud platforms makes the NPSA mission very achievable.

Taken together, strengthening of HIEs, the CMS move toward more timely quality measures, and expansion of The FDA Sentinel program provide ample precedent for the data collection needs of the NPSA to access the data needed to execute its mission. This includes Macro-tier surveillance, and the more comprehensive data required to support NTSB style analysis of harms, and conduct research and development of AI and automation that can reduce patient harms.

6. SURVEILLANCE TECHNICAL INFRASTRUCTURE

Similar to the data collection infrastructure, numerous capabilities exist today to accelerate making the vision of the NPSA a reality. The real-time surveillance envisioned for the NPSA can leverage existing capabilities from cybersecurity, existing healthcare system command and control centers, and existing public health surveillance capabilities. For maximum effect, surveillance infrastructure is needed both at the health system level (Meso-tier) and the industry level (Macro-tier).

More specifically:

- Cyber security centers such as already existing in the U.S. Military (Cyber Command), and for commercial communication vendors such as AT&T and Verizon.
- Healthcare Command Centers, such as those that exist today at Johns Hopkins Health System, Ascension Health System, and the Shenandoah regional command center.
- The CDC and DoD's public health surveillance infrastructure using the ESSENCE application.

Cybersecurity control centers are a good model for health and safety surveillance because of the focus on anomaly detection, identification of previously unseen patterns of suspicious behavior, and the need for rapid dissemination of threat information. These command centers also often monitor data from diverse sources across the ecosystem from dissimilar networks and infrastructures. While this kind of infrastructure is directly relevant to the threats that modern health systems face, the relevant analogy in the context of the NPSA is one that protects the patient vs. IT assets.

From Top Left Clockwise, U.S. Cyber Command, Norse Global Threat Surveillance, AT&T Cybersecurity Command Center, APL Health Engineering and Analytics Lab (HEAL) National Capital Area Pandemic Simulation using ESSENCE, eICU Tele Critical Care Control Center, Johns Hopkins Capacity Command Center.

Figure 8: Opportunity for Command Center Environments in Healthcare

Healthcare command centers have grown out of multiple applications for bed management and transport, to surgical center operations. The amount of digital data created by modern health system operations is substantial, and command centers are harnessing this data to optimize their operations and clinical performance. IHI has published guidance on creating such an infrastructure which includes not just optimization of operations to eliminate waste, but to integrate other system wide efforts like quality improvement (Ref. 36). While IHI stops short of advocating for patient safety, the central availability of system wide data makes the modern health system command center an ideal place to monitor and prevent patient harms in addition to ensuring best clinical practices.

Healthcare command centers that are focused on bed management and overall operations logistics are ideal for hosting patient safety focused applications because non-clinical administrative data can be a factor in patient harms. For example, not having the right resources (bed acuity level, staff, or other equipment) can cause risk to the patient. This information is not typically available in EHRs, population health, or precision health platforms, but is essential to identifying patient safety risks and rectifying them before patients are harmed. Together with AI and predictive capabilities like the Pascal Metrics PSAM platform, health systems have the opportunity to prevent harms before they happen. As with other functions of command centers, the information must be timely and accurate, and it must be presented in a manner to enable effective collective decision making, as well as presenting the right information locally at the point of care to take action. Healthcare command centers would benefit from adopting the principles of Common Operating Picture (COP), and Command, Control, and Communications (C3) architectures and decision tools.

Widespread surveillance with diverse data sources and real-time analytics are not new. The Centers for Disease Control (CDC) and Department of Defense (DoD) are leveraging the Electronic Surveillance System for Early Notification of Community based Epidemics (ESSENCE) to monitor data from a wide variety of sources to detect health related anomalies across the ecosystem.. ESSENCE has existed for 20 years and is in use across 47 states in the U.S. and as part of the National Syndromic Surveillance Program (NSSP) (Ref. 37). ESSENCE is also used by the Department of Defense for monitoring the National Capital Region (NCR) for bio-surveillance (Ref. 38).

ESSENCE collects data from 73 percent of Emergency Department visits in the country, in addition to data from labs, radiology, pharmaceutical benefit managers (PBM), nursing call centers, and over the counter sales. An advanced data analytics and visualization platform provides anomaly detection for early detection of and tracking of disease spread (Ref. 39). Applying this kind of technology platform to the charter of the NPSA could readily result in a national surveillance capability to support the NPSA mission by using these technologies for monitoring patient harms and preventing medical errors. These capabilities could also serve as a critical component of health system command and control centers. With lessons learned from the COVID-19 pandemic, it is essential that a broader investment is made to put in place a coherent infrastructure for surveillance, with tools like ESSENSE. This investment can be made in a way that lays the groundwork for the NPSA.

7. 21ST CENTURY INFRASTRUCTURE TO REDUCE PATIENT HARMS

The technology blueprint presented to support the mission of the NPSA is achievable with technology available today, in part due to the steady progress in healthcare interoperability and promotion of health information exchange by HHS of the along with the subsequent rollout of the EHR infrastructure, under the direction of the ONC from an interoperability perspective. Now that much of the data that drives our healthcare delivery system is digitized, it is imperative that the data be harnessed more effectively to make care safer for patients.

As laid out in the preceding white paper, this starts with a coherent and effective measurement system for patient safety events, based on data and not retrospective voluntary reporting, and not limited to just measurement of harms, but measurement rooted in safety science. This infrastructure will make unprecedented data available to guide decision making at a national level and setting priorities for maximum impact.

Data can also drive improvements in patient safety at the point of care, with more effective and automated monitoring of patients and thoughtful integration into the care delivery workflow at the point of care. This kind of automation and AI exists in many other industries with safety critical infrastructure, and needs to be an integral part of the healthcare infrastructure going forward. Simply put, healthcare needs more intelligent systems. More automation is coming, and the time is now to apply the systems engineering needed to leverage these new capabilities safely in healthcare. Establishing the NPSA now will allow healthcare policy and regulatory agencies to get ahead of this trend as more and more closed loop control of medical devices, and robotic assisted surgery is introduced to the healthcare industry.

Investing in the NPSA will also bolster the role of the national health information infrastructure, which has shown itself to be of great utility during the COVID-19 pandemic, and should be the highway upon which the NPSA collects data critical to measuring progress in the advancement of patient safety. The FDA's Sentinel program infrastructure, if properly expanded to include the right data, provides a sound basis for supporting the NPSA in meeting its research and development and investigative mission. Finally, the surveillance tools increasingly available to public health as well as health system command centers should be expanded to take advantage of tools available in other industries, with the communications, command, and control infrastructure needed to orchestrate operations to manage patient safety in addition to clinical operations.

The conceptual blueprint presented provides a framework from which the NPSA can be built with technologies that are available today. The blueprint is intended to serve as a guide to implementation of a comprehensive national infrastructure support improvements in patient safety in the next decade.

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APPENDIX A. WORLD HEALTH ORGANIZATION (WHO) PATIENT SAFETY CLASSIFICATION FRAMEWORK

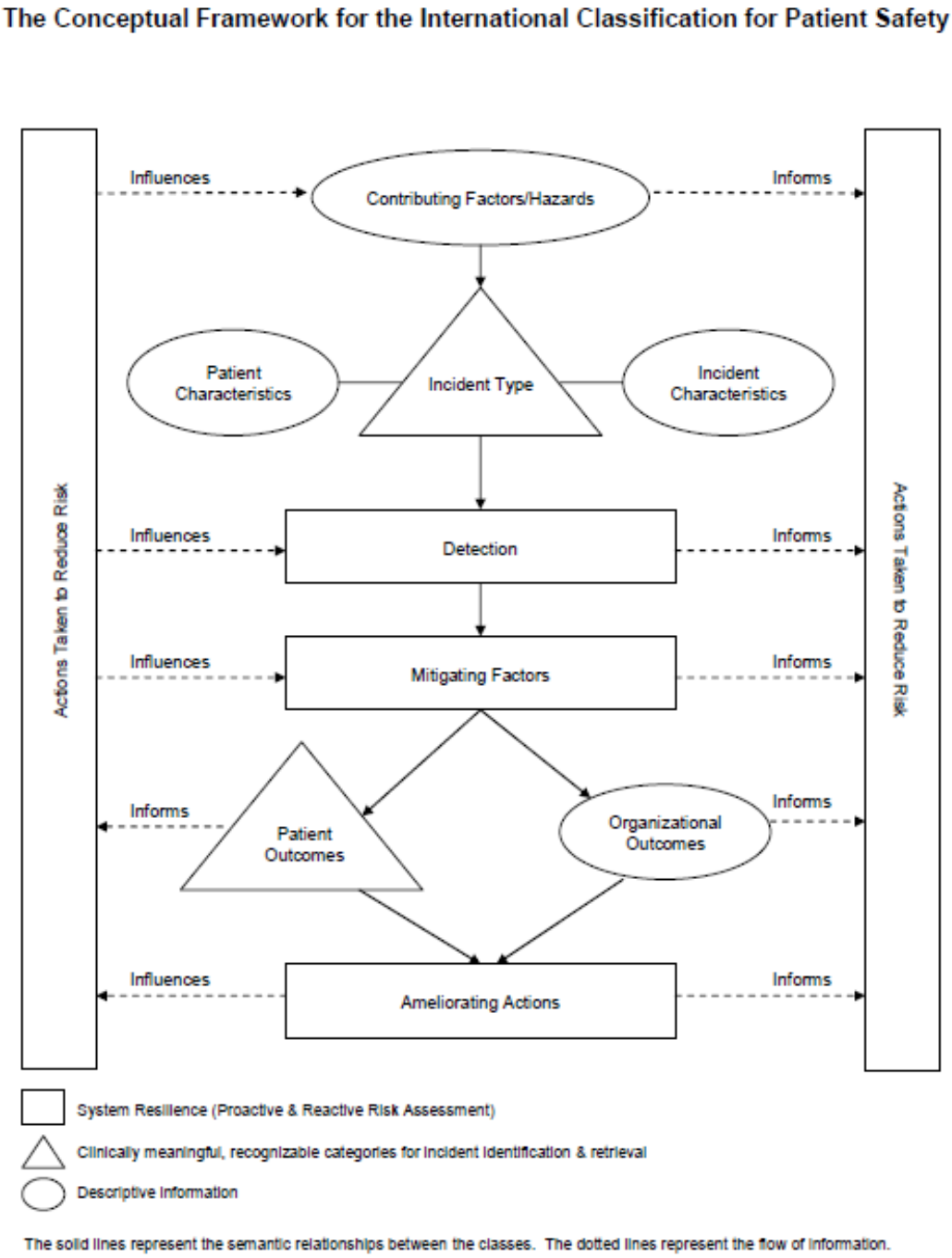

Figure A–1: WHO international classification of patient safety incident reporting 2009

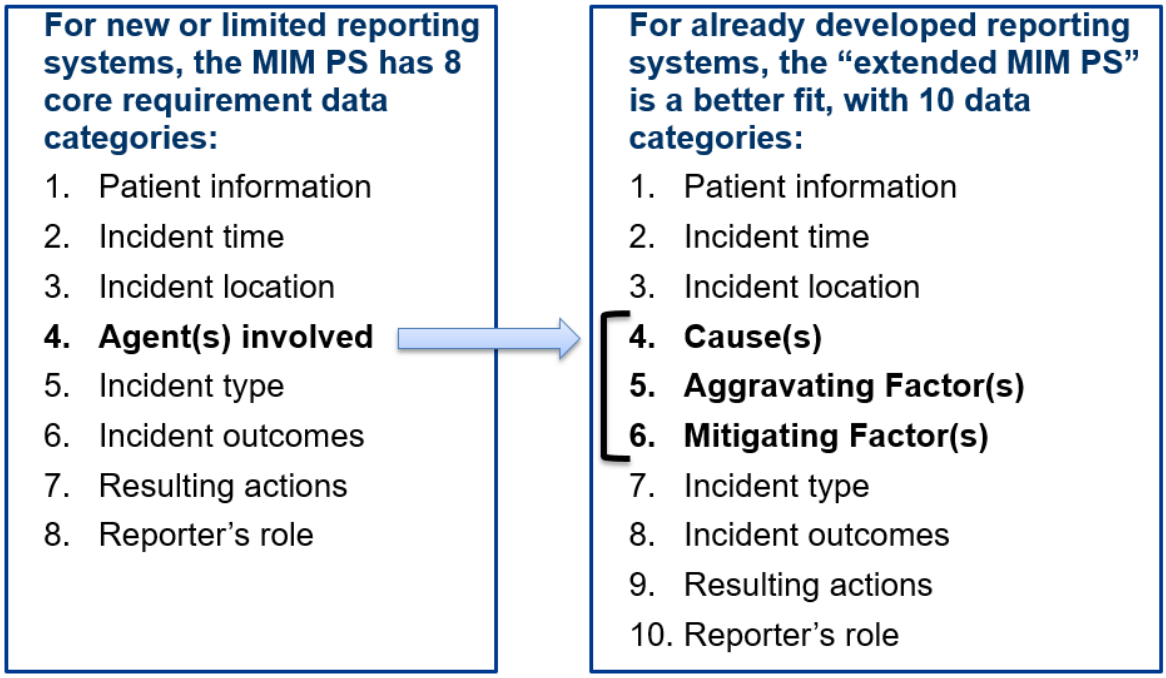

Figure A–2: Diagram by Jamie Yannayon based on WHO MIM PS European Validation Report May 2015

	Cares Module Triggers	+	Event Description and Harm Category (E-I)		Medication Module Triggers	+	Event Description and Harm Category (E-I)
C1	Transfusion or use of blood products			M1	*Clostridium difficile* positive stool		
C2	Code/arrest/rapid response team			M2	Partial thromboplastin time greater than 100 seconds		
C3	Acute dialysis						
C4	Positive blood culture			M3	International Normalized Ratio (INR) greater than 6		
C5	X-ray or Doppler studies for emboli or DVT						
C6	Decrease of greater than 25% in hemoglobin or hematocrit			M4	Glucose less than 50 mg/dl		
				M5	Rising BUN or serum creatinine greater than 2 times baseline		
C7	Patient fall						
C8	Pressure ulcers			M6	Vitamin K administration		
C9	Readmission within 30 days			M7	Benadryl (Diphenhydramine) use		
C10	Restraint use			M8	Romazicon (Flumazenil) use		
C11	Healthcare-associated infection			M9	Naloxone (Narcan) use		
C12	In-hospital stroke			M10	Anti-emetic use		
C13	Transfer to higher level of care			M11	Over-sedation/hypotension		
C14	Any procedure complication			M12	Abrupt medication stop		
C15	Other			M13	Other		
	Surgical Module Triggers				**Intensive Care Module Triggers**		
S1	Return to surgery			I1	Pneumonia onset		
S2	Change in procedure			I2	Readmission to intensive care		
S3	Admission to intensive care post-op			I3	In-unit procedure		
S4	Intubation/reintubation/BiPap in Post Anesthesia Care Unit (PACU)			I4	Intubation/reintubation		
S5	X-ray intra-op or in PACU				**Perinatal Module Triggers**		
S6	Intra-op or post-op death			P1	Terbutaline use		
S7	Mechanical ventilation greater than 24 hours post-op			P2	3rd- or 4th-degree lacerations		
				P3	Platelet count less than 50,000		
S8	Intra-op epinephrine, norepinephrine, naloxone, or romazicon			P4	Estimated blood loss > 500 ml (vaginal) or > 1,000 ml (C-section)		
S9	Post-op troponin level greater than 1.5 ng/ml			P5	Specialty consult		
				P6	Oxytocic agents		
S10	Injury, repair, or removal of organ			P7	Instrumented delivery		
S11	Any operative complication			P8	General anesthesia		
					Emergency Department Module Triggers		
				E1	Readmission to ED within 48 hours		
				E2	Time in ED greater than 6 hours		

Patient Identifier _____ Total Events _____ Total LOS _____ Write descriptions of the events in greater detail on reverse of Worksheet.

[Photocopy Worksheet single-sided. Leave opposite side blank for notes.]

Figure A–3: From IHI Global Trigger Tool White Paper 2009

APPENDIX B. INTEROPERABILITY AGENDA FOR THE NEXT DECADE

The NPSA will propel ONC efforts to drive the next layer of interoperability advances to insure that the measures can be consistently implemented across the EHR infrastructure. Figure B-1 and Figure B-2 frame highlight the opportunity for advancement which is worthy of fueling the interoperability agenda of HHS for the next decade.

As shown in Figure B-1, the focus has been on the underlying standards, and the technical, syntactic, and semantic layer of interoperability. Standardization on Fast Healthcare Interoperability Resources (FHIR) as a standard to extract data from EHRs, driven by anti-data blocking and CMS Interoperability Rule regulatory implementation timetables and maturing of the USCDI, will unleash innovation at the next layer of organizational interoperability. It is at this layer that standard best practices and risk-based measures can be implemented to promote patient safety and proactively prevent harms.

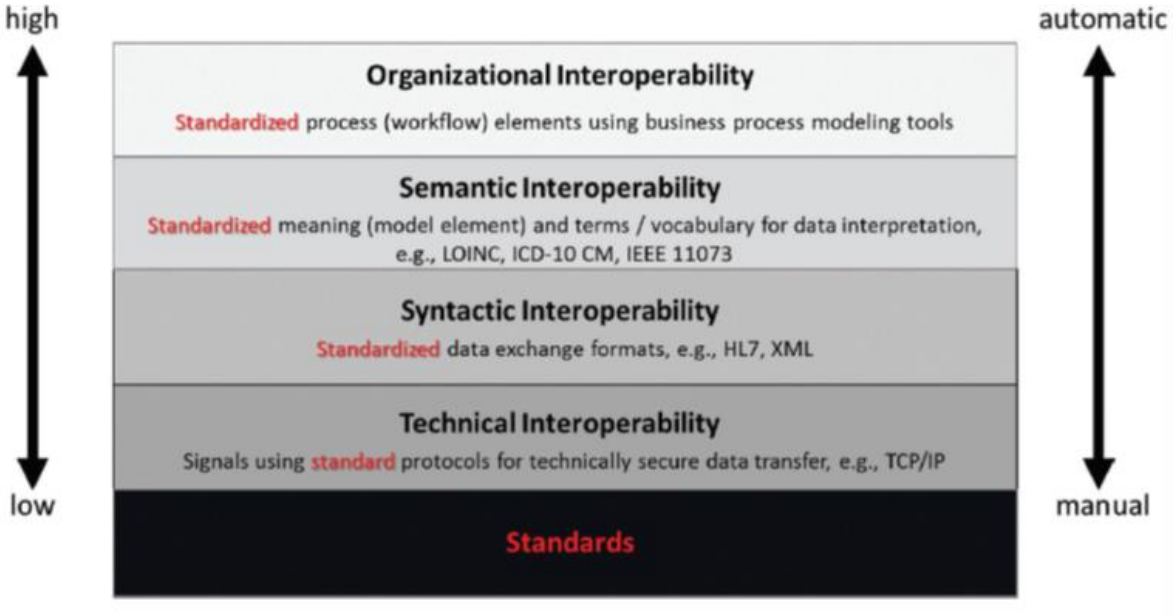

Figure B–1: Layers of Interoperability

While the ONC continues to drive efforts to achieve ubiquitous interoperability up to and including the semantic layer, including driving industry scalability of FHIR via the FHIR at Scale Taskforce (FAST), the NPSA can be the driving force behind more sophisticated use of data for preventing patient harms, and enabling more automation at the Organizational Layer. This is essential for predictive algorithms and AI driving increased healthcare industry automation to be scalable and usable across health systems.

Another useful way to consider this is via the interoperability maturity model developed by the Center for Medical Interoperability (C4MI), shown in Figure B-2. The ONC focus has been in infrastructure layers, and syntactic (integration standards) up to this point, and is still continuing

to drive terminology/semantic interoperability. In contrast, the NPSA will focus on the contextual/dynamic and orchestration components of the maturity model. The contextual/dynamic component, together with AI and the orchestration component is where risk based measures, error detection, and injury prevention intelligence will focus.

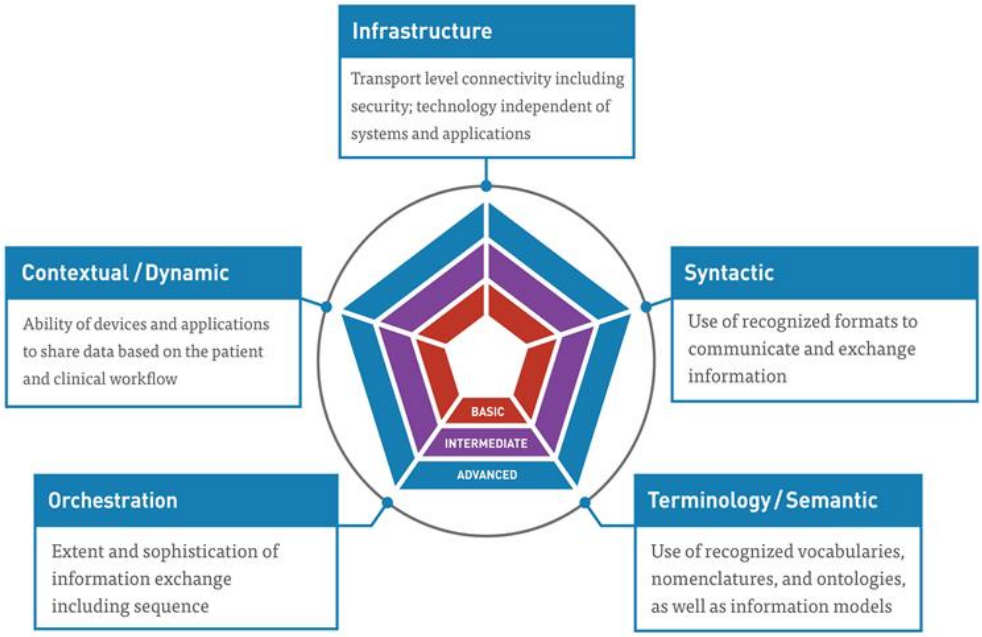

Figure B–2: Center for Medical Interoperability Maturity Model

It is expected that as value based contracting expands, both through the CMS Direct Contracting ACO model, and via pressure from commercial payers, that all health systems will need to create the interoperability layers shown. Most have already done so at the Micro-Tier layer with products like Capsule and Philips Intellibridge. Likewise, due to the heterogeneity of health systems, there are often many integration engines, like Orion Rhapsody or InterSystems, which support interoperability at the Meso-Tier.

There are even Macro-Tier infrastructures in place today in support of Health Information Exchanges and CMS and state reporting requirements. CMS and commercial payers are driving the need for more Macro-Tier integration in support of more effective and lower cost patient care. The NPSA can drive this further as medical errors that cause injury and complications will be increasingly transparent, and these costly events will not be tolerated, as the health system is more at risk.

APPENDIX C. ACRONYMS

ACO – Accountable Care Organizations
AHRQ – Agency for Healthcare Research and Quality
AI – Artificial Intelligence
APM – Alternate Payment Models
APL – Applied Physics Laboratory
ARRA - American Reinvestment and Recovery Act
C3 – Command, Control, and Communications
C4MI – Center for Medical Interoperability
CDC – Center for Disease Control
CDS – Clinical Decision Support
CMMI – Center for Medicare and Medicaid Innovation
CMS – Center for Medicaid and Medicare Services
COP – Common Operating Picture
CORHIO – Colorado Regional Health Information Organization
CPA – Cardiopulmonary Arrest
CPOE – Computerized Physician Order Entry
CRISP – Chesapeake Regional Information System for Patients
DHA – Defense Health Agency
DIACC – Device Interoperability and Autonomy Coordinating Center
DoD – Department of Defense
eCQMs – Electronic Clinical Quality Measures
EHR – Electronic Health Record
EMR – Electronic Medical Record
ESSENCE – Electronic Surveillance System for Early Notification of Community-based Epidemics
FAST – FHIR at Scale Taskforce
FDA – Food and Drug Administration
FDAAA – FDA Amendments Act
FHIR – Fast Healthcare Interoperability Resources
FMEA – Failure Modes and Effects Analysis
GLHC – Great Lakes Health Connect
GTT – Global Trigger Tool
HAC – Hospital Acquired Condition
HIE – Health Information Exchange
HITECH - Health Information Technology for Economic and Clinical Health Act
HHS – Health and Human Services
ICPS – International Classification for Patient Safety
ICU – Intensive Care Unit
IHI – Institute of Healthcare Improvement
IHIN – Iowa Health Information Network
JHF – Jewish Healthcare Foundation
JSER – Joint Commission Sentinel Events Reporting Database
MDIRA – Medical Device Interoperability Reference Architecture

MEWS – Modified Early Warning Systems
MiHIN – Michigan Health Information Network
MIM PS – Minimal Information Model of Patient Safety
MIPS – Merit-based Incentive Payment System
ML – Machine Learning
MRDC – Medical Research and Development Command
NCCMERP – National Coordinating Center for Medication Error Reporting and Prevention
NCR – National Capital Region
NEHI – Network for Excellence in Health Innovation
NEHII – Nebraska Health Information Initiative
NETCCN – National Emergency Tele Critical Care Network
NHMA – National Health Mission Area
NPSA – National Patient Safety Authority
NSSP – National Syndromic Surveillance Program
NTSB – National Transportation Safety Board
ONC – Office of the National Coordinator
PBM – Pharmaceutical Benefit Managers
PDMP – Prescription Drug Monitoring Program
PRHI – Pittsburgh Regional Health Initiative
PSAM – Patient Safety Active Management System
PSET – Joint Commission Patient Safety Event Taxonomy
PSO – Patient Safety Organizations
PTFP – Preliminary Taxonomy of Medical Errors in Family Practice
R&D – Research and Development
RRT – Rapid Response Teams
RWE – Real World Evidence
SHIEC – Strategic HIE Collaborative
TATRC – Telemedicine and Advanced Technology Research Center
TEFCA – Trusted Exchange Framework and Common Agreement
TiDE – Technology in Disaster Environments
TREWScore – Targeted Real-time Early Warning Score
USCDI – United States Core Data for Interoperability
WHO – World Health Organization